# 510(k) Summary

K 062000

**Company** Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

SEP 25 2006

**Contact** Carol Wash, RAC
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**Date Prepared** July 12, 2006

**Device Name**

| | |
|---|---|
| Trade Name: | Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control |
| Common or Usual Name: | Instrument, Ultrasonic Surgical |
| Classification Name: | Unclassified |

**Predicate Devices** Harmonic Blades and Shears Expanded Indication
Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control
Harmonic 5mm Curved Shears with Scissor Grip

**Device Description** The Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control is a sterile, single patient use instrument consisting of a scissor handle housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level). The handle housing has an integrated audible/tactile mechanism for indicating full closure. The instrument has a straight blade and clamp arm and is designed to function through an incision without the use of a trocar. The instrument is 18cm long with a shaft diameter of 8.5mm and an active blade length of 18mm.

**Indications for Use** The Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure of orthopedic structures (such as spine and joint space) and other open procedures.

**Technological Characteristics** The Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control is similar to the design of the predicate device, the Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control. The new device is different from the predicate device in that it is designed for efficiency in performance of open surgical procedures.

**Performance Data.** Bench testing and preclinical laboratory evaluations were performed to demonstrate that the new device performs as intended. In vivo animal testing has shown the ability of the Harmonic WAVE™ Coagulating Shears to seal arteries less than or equal to 5mm in diameter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2006

Ethicon Endo-Surgery, Inc
% Carol Walsh, RAC
Associate II, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K062000
Trade/Device Name: Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control
Regulation Name: Unclassified
Product Code: LFL
Dated: July 12, 2006
Received: July 17, 2006

Dear Ms. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K062000

Device Name: Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control

Indications for Use:

The Harmonic WAVE™ Coagulating Shears with Scissor Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K062000